

EXHIBIT A

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

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THE HONORABLE JAMES V. SELNA, JUDGE PRESIDING

IN RE FONTEM US, INC.,)
CONSUMER CLASS ACTION)
LITIGATION:) SACV-15-01026-JVS
-----) Consolidated with:
SACV-15-02018-JVS

REPORTER'S TRANSCRIPT OF PROCEEDINGS

Santa Ana, California

September 15, 2016

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United States Courthouse
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1 SANTA ANA, CALIFORNIA; MONDAY, SEPTEMBER 15, 2016; 9:59 A.M.

09:59 2 THE COURT: Item No. 2, SACV-15-01026-JVS, In Re
09:59 3 Fontem Consumer Class Action Litigation consolidated with
09:59 4 SACV-15-2018-JVS.

09:59 5 Counsel, please state your appearances for the
09:59 6 record.

09:59 7 MR. GABRIEL: Good morning, Your Honor. Allan
09:59 8 Gabriel representing all of the defendants.

10:00 9 MR. TODZO: Good morning, Your Honor. Mark Todzo
10:00 10 representing the plaintiffs.

10:00 11 MR. BELIGAN: Good morning, Your Honor. Jerusalem
10:00 12 Beligan on behalf of the plaintiffs.

10:00 13 THE COURT: Good morning.

10:00 14 I trust you have all had a chance to review the
10:00 15 tentative.

10:00 16 MR. TODZO: Yes, Your Honor.

10:00 17 MR. GABRIEL: Yes, Your Honor.

10:00 18 THE COURT: Who is going to argue on behalf of the
10:00 19 plaintiffs?

10:00 20 MR. TODZO: I will.

10:00 21 THE COURT: Okay. Mr. Todzo.

10:00 22 MR. TODZO: Thank you, Your Honor.

10:00 23 Thank you for the tentative. I think that gives
10:00 24 us a lot of interesting questions to discuss today. The
10:00 25 first few things I would like to discuss are things that

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10:00 1 really weren't brought out in the papers, but one thing that
10:00 2 kind of struck me when I looked at the end result of your
10:00 3 tentative and also at the first footnote of your
10:01 4 tentative --

10:01 5 THE COURT: Are you telling me you now have
10:01 6 arguments that aren't reflected in your papers?

10:01 7 MR. TODZO: I have two, yes. One is timing
10:01 8 related, and one relates to the opinion that Judge Carter
10:01 9 issued after all of briefing came down. And the remainder
10:01 10 of my arguments just directly relate to the specific issues.

10:01 11 With respect to the timing, Your Honor cites the
10:01 12 effective date at Footnote 1 on page two of the tentative.
10:01 13 And the effective date for the particular FDA requirement
10:01 14 that Your Honor found preempted is May of 2018. And
10:01 15 that raises an interesting question, which is can an
10:01 16 ineffective -- because it's ineffective today -- can an
10:01 17 ineffective federal requirement preempt a state law
10:01 18 today?

10:01 19 When I went back before -- and there is no
10:01 20 specific definition of a requirement in the federal act, but
10:01 21 "requirement" is a common usage term. When I looked at the
10:02 22 definitions of "requirement," they are all present. They
10:02 23 are all present tense: that which is required, a thing that
10:02 24 is demanded or obligatory. So those all imply that there
10:02 25 has to be a present aspect to the particular federal

10:02 1 requirement. And the fact that it doesn't take effect for
10:02 2 two years, it seems as though this is almost like an
10:02 3 advisory type opinion because -- frankly, it's actually very
10:02 4 good to know Your Honor's position, that when the
10:02 5 requirement takes effect in 2018 that it would be preempted
10:02 6 because that may affect certain remedies that would be
10:02 7 available. That's the first issue.

10:02 8 I think it's actually quite similar to the way
10:02 9 Your Honor looked at this issue -- or at least the primary
10:02 10 jurisdiction issue during the first hearing, which was
10:03 11 saying, look, it's premature because the rule hasn't been
10:03 12 finalized. Well, now the rule has been finalized, but the
10:03 13 requirement is defective, so there is definitely some
10:03 14 tension there.

10:03 15 The second timing-related issue is with respect to
10:03 16 sort of the conclusion at the end of the tentative, which is
10:03 17 dismissing all of the claims other than the Prop 65-related
10:03 18 claim with prejudice. Now, the problem there is that those
10:03 19 claims -- all those other claims are claims for damages,
10:03 20 injunctive relief -- well, damages, injunctive relief, but
10:03 21 also restitution.

10:03 22 The damages and restitutionary portions of those
10:03 23 claims all relate back. Most of them have a four-year
10:03 24 statute of limitations. So the limitations period actually
10:03 25 begins in 2011. So there is a period from 2011 until --

10:03 1 let's assume for a second that the ineffective requirement
10:04 2 is essentially preempted as of its publication date. So at
10:04 3 a minimum, you have a period from 2011 up through May 10 I
10:04 4 believe of 2016 when the rule was finalized during which
10:04 5 there was no federal requirement in place.

10:04 6 I think again this sort of relates to when Your
10:04 7 Honor looked at the issue of primary jurisdiction back
10:04 8 before the FDA even had jurisdiction, before the TCA covered
10:04 9 the particular products that are at issue in this case.
10:04 10 There could be no primary jurisdiction because there was no
10:04 11 jurisdiction.

10:04 12 THE COURT: Well, certainly not on the basis of
10:04 13 regulations that haven't gone into effect. That's your
10:04 14 point. Yes.

10:04 15 MR. TODZO: Exactly. So now only as a result of
10:04 16 the regulations having taken effect -- only as a result of
10:04 17 that does the Tobacco Control Act now cover electronic
10:04 18 cigarette products. But it's undisputed that prior to
10:05 19 May 2016 those products were not regulated at all by the
10:05 20 federal government. That's undisputed. So it was only as
10:05 21 of May 2016 when the reg was finalized that now all of
10:05 22 a sudden there is actually TCA regulation for those
10:05 23 products; and, therefore, now, you can apply the preemption
10:05 24 provision.

10:05 25 But applying the preemption provision to a claim

10:05 1 that arose in 2011 when the statute didn't apply to those
10:05 2 claims, that's a retroactive application. There is nothing
10:05 3 in the congressional record. There is nothing in the Act
10:05 4 itself that says -- or certainly nothing in the new rule
10:05 5 that says not only do we intend for this rule to be
10:05 6 preempted -- as I will get to later, the FDA doesn't
10:05 7 say --

10:05 8 THE COURT: Well, they don't say.

10:05 9 MR. TODZO: Well, we will get there. I mean,
10:05 10 I think their statement that no law that was presented to
10:06 11 them would be preempted by the rule is a statement that
10:06 12 there is no preemption. Like I say, I will get to that in a
10:06 13 minute.

10:06 14 With respect to the retroactive application, there
10:06 15 is nothing in their rule that says that rule should be
10:06 16 retroactively applied. In fact, it's not even applied
10:06 17 today. It's applied two years in the future.

10:06 18 So I think at a minimum assuming you reject
10:06 19 everything else I'm going to say here forward -- I think at
10:06 20 a minimum Your Honor has to adjust the final conclusion and
10:06 21 determine that the preemption can occur only from -- you
10:06 22 know, either the date the rule was finalized or the date
10:06 23 that the requirement takes effect. It's one of those two
10:06 24 dates. That can't possibly be preemption dating back prior
10:06 25 to that.

1 Even if Your Honor were to think that there's a
2 possibility that there could be retroactive application of
3 the preemption provision, it's the defendants' burden to
4 prove that. I think one of the basic tenets of preemption
5 law is that absent the clear and manifest intent of Congress
6 there is no preemption of state laws. That's especially
7 true whereas here we are talking about a provision of a
8 state law that covers health and safety. So that's where
9 that strong presumption against preemption applies.

10 In the face of a strong presumption against
11 preemption, you have got a law that at best takes effect in
12 May of 2016, possibly May of 2018. So, again, there is
13 nothing there that could say that it could preempt something
14 going back as far as 2011 or even 2015 or even April of
15 2016.

16 One of the reasons why that gap between 2016 and
17 2018 could be potentially outcome determinative here is
18 there have been no less than five lawsuits filed challenging
19 the regs already. I know that's not in the record. If Your
20 Honor would like, I do have a supplemental request for
21 judicial notice that just gives you the docket numbers so
22 you will see there are five different cases challenging the
23 enactment of these regs.

24 If at any time between today or May of 2016 and
25 May of 2018 the regs are either kicked out or if some aspect

1 of those are kicked out, then the requirement will never
2 take effect. And if a requirement never takes effect, can
3 that then have a preemptive effect? That's another
4 interesting question, which I think the best way to
5 determine that is even if Your Honor sticks with the idea
6 that the reg is preempted, it would only be preempted from
7 May of 2018 forward.

8 So those are the two timing-related issues I
9 wanted to touch on.

10 With respect to Judge Carter's ruling, I apologize
11 that we got it to you so late. Don't know if you have had
12 an opportunity to look at it, but Judge Carter in the Five
13 Palms case --

14 THE COURT: Well, he took a fairly narrow view of
15 what labeling related to.

16 MR. TODZO: That's exactly right. I found that
17 sort of interesting.

18 THE COURT: I'm not sure it's supported by the
19 statute, however.

20 MR. TODZO: Your Honor, I have looked at it with
21 the same interest as to where he was finding that. He
22 certainly doesn't describe exactly where he found it, but
23 there is some textual support in the statute. What I think
24 you have to do is you have to compare -- so you know how the
25 TCA -- it's called preservation of state authority. That

10:10 1 provision has three subdivisions. One is the initial
10:10 2 preservation of state authority provision. Then it has the
10:10 3 preemption provision. And then it has the exception from
10:10 4 preemption provision.

10:10 5 So when you look at the initial preservation
10:10 6 language -- this is 21 USC 387p(a)(1). It says: "Except
10:10 7 as provided in paragraph 2(a)" -- that's the presumption
10:10 8 provision -- "nothing in the subchapter or rules promulgated
10:10 9 under the subchapter shall be construed to limit." So it
10:10 10 uses the language "subchapter or rules promulgated under
10:10 11 the subchapter." That would imply that there is the
10:10 12 statutory provisions. That's under the subchapter. And
10:10 13 then there are the rules promulgated under the subchapter,
10:10 14 which would be things like FDA requirements promulgating the
10:11 15 rules.

10:11 16 Then when you look to the preemption provision,
10:11 17 that language, "rules promulgated under the subchapter," are
10:11 18 absent. It just says, "which is different from or in
10:11 19 addition to a requirement under the provisions of this
10:11 20 subchapter."

10:11 21 So what I was try to figure out if there is
10:11 22 textual support for what Judge Carter did, that's where I
10:11 23 think you find it, that the preemption provision seems to
10:11 24 limit itself to the actual statutory enactments. So when
10:11 25 you look at the statutory enactments --

10:11 1 THE COURT: Wouldn't that be kind of silly? You
10:11 2 know, if the statute preempts conduct or attacking conduct
10:11 3 and there are regulations implementing the preemptive
10:11 4 statute and there is authority to issue those regulations,
10:11 5 would it be kind of silly to conclude that the regulations
10:11 6 aren't preempted?

10:11 7 MR. TODZO: Well, Your Honor, there is always
10:11 8 implied preemption. There is also conflict preemption. So
10:12 9 a reg would have a conflict preemptive effect to the extent
10:12 10 it conflicted with state law. But I think when I look at
10:12 11 what Congress did -- again, there is a limited congressional
10:12 12 record on this. There is not a great amount of legislative
10:12 13 history, but there is some. And the alleged history that we
10:12 14 cited in our brief talks about the idea that Congress really
10:12 15 wanted to limit the preemptive effect of the statute.

10:12 16 I think what happened was so many cigarette
10:12 17 labeling cases, so many cigarette cases, were preempted that
10:12 18 Congress wanted to be careful that there was a federal and
10:12 19 state partnership with respect to tobacco products. So when
10:12 20 I believe it was the House report -- we cited this in our
10:12 21 brief. The quote is that: "An important part of this bill
10:12 22 was actually to remove one of the obstacles that now exist
10:13 23 to more aggressive regulation at the state and local level
10:13 24 by loosening the preemption and allowing states to engage in
10:13 25 regulations that supplement whatever federal regulations are

10:13 1 adopted."

10:13 2 So the idea is that the -- Congress is aware of
10:13 3 what they were doing. They expressly preempt as to their
10:13 4 specific enactments. But when it comes to regulatory
10:13 5 enactments, yes, there is always going to be conflict
10:13 6 preemption, but they didn't intend for those to have an
10:13 7 express preemptive effect. That marries the concept of
10:13 8 limiting the overall preemptive effect of the statute, which
10:13 9 was the congressional goal. And it really marries then the
10:13 10 idea that the FDA had, which is, look, this is a minimum
10:13 11 warning requirement because that's again what Congress would
10:13 12 have intended.

10:13 13 So those are the timing-related issues.

10:14 14 One thing I should mention about Judge Carter is
10:14 15 that -- I'm only aware of three cases that have ruled on TCA
10:14 16 preemption. We cited two of them in our brief, which is the
10:14 17 U.S. Smokeless Tobacco case and the National Advertiser
10:14 18 case. One of them, the U.S. Smokeless case, was the Second
10:14 19 Circuit. The National Advertiser case is the First Circuit.
10:14 20 And now you have Judge Carter. So of the three decisions on
10:14 21 TCA preemption, all have decided that there is no
10:14 22 preemption.

10:14 23 I understand that every requirement is different,
10:14 24 and the preemption analysis is sometimes unique to the
10:14 25 particular claim. But it's just interesting to note that

10:14 1 every judge to look at TCA preemption has so far found that
10:14 2 there is no preemption.

10:14 3 Now moving on to the specific arguments that you
10:15 4 address head on, we have this issue as to whether the
10:15 5 particular labeling -- or I guess what it is called is the
10:15 6 minimum warning requirement within the final rule -- whether
10:15 7 that is a specific enough requirement to trigger preemption
10:15 8 under the Medtronic and Regal cases and the case you cited,
10:15 9 the Papike case.

10:15 10 What I think happened is I believe that Your Honor
10:15 11 conflated the specificity of the warning itself, the
10:15 12 language, with the specificity of the application of the
10:15 13 particular requirement. So when I look back at the
10:15 14 Medtronic case and the Regal case, which further explained
10:15 15 Medtronic, and even the Papike case, in each of those
10:15 16 instances, the distinction was whether a requirement was
10:15 17 specific as to a particular device or whether it was general
10:16 18 as to all devices or a whole group of devices.

10:16 19 So when in Medtronic the only applicable
10:16 20 regulations were the general ones, the ones that apply to
10:16 21 all medical devices as opposed to in Regal where there was
10:16 22 the premarket approval -- so not only was it specific as to
10:16 23 the particular type of device, but it was actually specific
10:16 24 as to that manufacturer's specific device. You know, the
10:16 25 specific skew would be the equivalent in a consumer product.

1 Then with Papike it was specific as to Tampons. It wasn't
2 one of the general labeling requirements.

3 What I actually found helpful, if you look at --
4 there is an exhibit that the defendants submitted with their
5 Request for Judicial Notice. There is a labeling manual
6 that was submitted as Exhibit B to I believe Mr. Gabriel's
7 declaration or the Request for Judicial Notice. It was ECF
8 74-2. This is a labeling guide for medical devices from the
9 FDA. When I looked at it, it has this distinction between
10 the general device labeling -- in terms of page number, I'm
11 going to go with the exhibit page number. It's Exhibit B,
12 page 20.

13 It has what is called "General Device Labeling,"
14 and the introductions says: "These regulations specify the
15 minimum requirements for all devices." Then it goes on --
16 in Exhibit B at page 25, it gets into labeling requirements
17 for specific devices. And, of course, one of the specific
18 devices that it talks about menstrual Tampons, and it talks
19 about how there is a specific warning requirement.

20 So the upshot is when you have the general
21 requirements that apply to all products within a category,
22 those are not preempted. But then when the FDA looks at the
23 specific device or the specific product and then issues
24 regulations concerning that product, those would be
25 preempted.

10:18 1 So here when you look at the new regs or the 21
10:18 2 CFR 1143.3(a), by its own terms, it applies to cigarettes;
10:18 3 smokeless tobacco; and all covered tobacco products, which
10:18 4 includes gels, dissolvables, water pipe tobacco, pipe
10:19 5 tobacco, e-cigarettes, including refillable personal
10:19 6 vaporizers, vape pens, and e-cigarettes themselves. So it
10:19 7 applies to the entire class.

10:19 8 Yes, it is a specific -- there is specific warning
10:19 9 language. But I don't think that's in essence any different
10:19 10 than when they have specific -- a statement that says you
10:19 11 have to put the origin in the labeling. You have to say
10:19 12 this product is manufactured by and add the manufacturer's
10:19 13 name. That the general labeling requirements that they were
10:19 14 talking about in Medtronic. So that's the difference.

10:19 15 Again, I think when you look at it it makes sense
10:19 16 then. It's consistent with the FDA's policy of having
10:19 17 general requirements being, quote, "minimum requirements"
10:19 18 for them to title that particular regulation as a minimum
10:19 19 requirement. It's exactly what they did with respect to the
10:20 20 general device labeling.

10:20 21 There are a couple of other things on this point.
10:20 22 In your tentative on page four, there was a statement in the
10:20 23 second paragraph under Subsection (A). Your Honor says
10:20 24 that: "The Court observes that the clear and unambiguous
10:20 25 language of the preemption provision of the TCA preempts

10:20 1 states from requiring any particular labeling of tobacco
10:20 2 products." So I think when Your Honor is looking at it in
10:20 3 those terms that's very overbroad because that's not the
10:20 4 language of the provision. The language of the provision is
10:20 5 going to preempt only where there is a federal requirement
10:20 6 in place as to that particular product.

10:20 7 That's again the crux of the difference. We are
10:20 8 not talking about just because there is a labeling -- a
10:21 9 potential labeling requirement that does apply to
10:21 10 e-cigarettes in addition to all other tobacco products, you
10:21 11 know, that that now preempts all labeling requirements. In
10:21 12 essence, that would preempt all labeling as to cigarettes,
10:21 13 smokeless tobacco, all the ones I mentioned, gels,
10:21 14 dissolvables. I think that's way overbroad.

10:21 15 There is one other statement at the bottom of page
10:21 16 four where you said: "The FDA has promulgated a labeling
10:21 17 requirement for e-cigarettes." Again, I don't think that's
10:21 18 quite accurate because the FDA has promulgated a labeling
10:21 19 requirement for all tobacco products. Again, that's where
10:21 20 the distinction lies.

10:21 21 The next thing I wanted to talk about was the
10:22 22 exemption. I understand Your Honor looks at the claims and
10:22 23 says, look, all these claims relate to failure to warn. I
10:22 24 agree. We can't hide from that.

10:22 25 THE COURT: Indeed, that's what you are putting

10:22 1 forward.

10:22 2 MR. TODZO: Right. Our case is essentially that
10:22 3 the defendant has failed to disclose hazards associated with
10:22 4 use and exposure to their products. That's what our case is
10:22 5 about. So there are two aspects to the case. On the one
10:22 6 hand show, we are going to have to show that use and
10:22 7 exposure of the products results in some type of harm that
10:22 8 the defendant had a duty to disclose, and they didn't do it.
10:22 9 So there is the use and exposure portion of the case. And
10:22 10 there is the failure to disclose or broadly stated a
10:22 11 labeling-type piece. So it relates to both.

10:23 12 So now what do you do? I'm sort of going on the
10:23 13 assumption now that the preemption provision can extend to
10:23 14 FDA's requirements. So there is the first part that Judge
10:23 15 Carter viewed that it only extends to statutory
10:23 16 requirements, but let's talk for a second as if it applied
10:23 17 to the FDA's requirements and assuming that it is a specific
10:23 18 enough requirement.

10:23 19 So now you have a requirement that relates to both
10:23 20 the preemption and to the exemption. So in that case, what
10:23 21 do you do? And I think that the two Circuit Court cases,
10:23 22 both the U.S. Tobacco case and the National Association of
10:23 23 Tobacco Outlets case -- should I give the cites for those
10:23 24 for the record? They're in the briefs.

10:24 25 THE COURT: They're in the briefs.

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10:24 1 MR. TODZO: Anyway, in both of those cases, they
10:24 2 said, look -- the claims at issue there, which were whether
10:24 3 a particular state can ban the sale of flavored tobacco
10:24 4 products -- so it relates to tobacco product standards
10:24 5 because whether or not a tobacco product is flavored is a
10:24 6 standard relating to the particular product. And, indeed,
10:24 7 there were regulations concerning flavorings, but it also
10:24 8 relates to the sale and distribution of the products. So
10:24 9 the Court said, well, when it arguably relates to both, you
10:24 10 have got to go with the exemption because -- the Courts
10:24 11 basically conclude you give broad effect to the exemption,
10:24 12 and you narrowly construe the preemption provision.

10:24 13 I'm not sure they explain exactly why, but I think
10:24 14 it's clear that -- again, we are talking about preemption.
10:25 15 We are talking about where it has to be the clear and
10:25 16 manifest intention of Congress to preempt a particular type
10:25 17 of claim. And there is a strong presumption against
10:25 18 preemption of a health and safety matter. So in those
10:25 19 instances where something arguably relates to both exposure
10:25 20 and labeling, I think you have to go with the exemption
10:25 21 because that's more consistent with the exemption from
10:25 22 preemption.

10:25 23 The one claim in particular that I wanted to touch
10:25 24 on with respect to exposure is Prop 65. That is the essence
10:25 25 of the claim under Prop 65. When you look at the statutory

10:25 1 provision under which the claim was brought, it specifically
10:25 2 says: "No person in the course of doing business shall
10:25 3 knowingly and intentionally expose any individual to a
10:25 4 chemical known to the State to cause cancer without
10:26 5 providing the clear and usable warning." So on its face, it
10:26 6 has both. It has both the warning piece and the exposure
10:26 7 piece.

10:26 8 Indeed, one of the things -- Prop 65 is somewhat
10:26 9 unique in that there is a big burden on the defendant, not a
10:26 10 huge burden on the plaintiff thankfully, where what we need
10:26 11 to show is that there is exposure, any exposure at all, to
10:26 12 the particular chemical here, formaldehyde. So that's all
10:26 13 we are going to need to show.

10:26 14 Then the burden is going to shift to the
10:26 15 defendant. And that's the burden -- we talk about that in
10:26 16 Health and Safety Code 25249.10(c), which is known as the
10:26 17 exposure defense. And that's where they are going to need
10:26 18 to come with evidence to show that any of the exposures are
10:26 19 below the threshold requiring the warning. So the whole
10:26 20 case is fought out about exposure.

10:26 21 Indeed, when you look at the definition of
10:26 22 "consumer product exposure" in the regs -- I know the
10:26 23 defendant says we are talking about exposure to a chemical
10:27 24 and not the product. That's a distinction they draw, but
10:27 25 that's not a distinction that Prop 65 looks at because Prop

10:27 1 65 says: "A consumer product exposure is an exposure that
10:27 2 results from a person's acquisition, purchase, storage,
10:27 3 consumption, or other reasonably foreseeable use of a
10:27 4 consumer good." So it's of the good itself. I just don't
10:27 5 think that it's correct to sort of gloss over that piece.

10:27 6 I think the way Your Honor was looking at it is
10:27 7 what's the gravamen of the claim? Is this claim based on
10:27 8 exposure, or is it based on labeling? But that's not the
10:27 9 language of the preemption provision or the exemption
10:27 10 provision. They use "relate to." I know there are some
10:27 11 statutes -- I believe the Cigarette Labeling Act actually
10:28 12 uses the "based on" language. It's based on smoking and
10:28 13 health. But that's not the case here. We are talking about
10:28 14 relating to. I think it's very tenuous to say that these
10:28 15 claims don't relate to exposure when that's actually part of
10:28 16 our burden, which is to show exposure and use somehow
10:28 17 results in some harm that needed to be disclosed or warned
10:28 18 for.

10:28 19 On the labeling issue -- and I think Your Honor
10:28 20 went obviously the right way on that issue in terms of Prop
10:28 21 65 and whether or not it constitutes labeling. The one
10:28 22 thing I would like to point out is that the AMI case, the
10:28 23 Lemman case -- in that case, they used that very, very broad
10:28 24 definition of "labeling," which is anything that supplements
10:28 25 or explains the product, which I think arguably would extend

10:29 1 to all advertising for the product.

10:29 2 Indeed, back to that FDA Labeling Guide that I
10:29 3 mentioned before, the FDA when construing other aspects of
10:29 4 the FDCA does talk about -- this is again Exhibit B to the
10:29 5 Gabriel declaration. At page three, it says: "According to
10:29 6 an appellate court decision, most, if not all, advertising
10:29 7 is labeling. The term 'labeling' is defined in the FDC to
10:29 8 include all printed matter accompanying an article.
10:29 9 Congress did not and we cannot exclude from the definition
10:29 10 printed matter which constitutes advertising."

10:29 11 So I can understand why Leman in its case went
10:29 12 with that broad definition which would sweep all advertising
10:30 13 within the guise of labeling. The problem is here we can't
10:30 14 because Congress drew a distinction between labeling on the
10:30 15 one hand and advertising on the other because it included
10:30 16 labeling in the preemption -- the matter which is preempted,
10:30 17 but it excluded advertising. So some printed matter that
10:30 18 accompanies an article is preempted. Some printed matter
10:30 19 that accompanies an article is not preempted.

10:30 20 I think that's another reason why it doesn't make
10:30 21 sense to follow the Leman case here. Leman -- again, for
10:30 22 the Meat Inspection Act, that might be fine, but with
10:30 23 respect to the Tobacco Control Act, you just can't give such
10:30 24 a broad reading to the term "labeling." Again, of course we
10:30 25 have what Judge Carter did, which is a very restricted view.

10:31 1 And then the last point I wanted to make has to do
10:31 2 with the FDA's interpretation of the rule itself. Your
10:31 3 Honor obviously has a view on that. The difficulty I have
10:31 4 is when I look at the comments and then I look at the
10:31 5 response -- when you look at the comments, the FDA
10:31 6 specifically says: "A number of comments sought an
10:31 7 affirmative statement from the FDA that the NPRM would
10:31 8 preempt state and local warning requirements." A few of the
10:31 9 comments directly reference California's health requirements
10:31 10 for products containing nicotine, a notice required by Prop
10:31 11 65."

10:31 12 So then the FDA goes through, and they analyze the
10:31 13 scope of the TCA. And then the FDA concludes: "No state or
10:31 14 local laws in effect at the close of the public comment
10:31 15 period were identified that the FDA determined would be
10:32 16 preempted by this final rule." So that is a statement.
10:32 17 That is a statement with respect to the particular state
10:32 18 laws that were presented. Then we had the separate comment
10:32 19 from the 29 Attorneys General who said we want a statement
10:32 20 that says these aren't preempted.

10:32 21 Well, what more could they be asking for than this
10:32 22 statement saying that they are not preempted? That's
10:32 23 exactly what the commenter on the AG side was looking for
10:32 24 and what the commenter on the industry side was looking to
10:32 25 get the opposite. If the industry had gotten the statement

10:32 1 saying that Prop 65 is preempted, well, I'm sure Mr. Gabriel
10:32 2 would have been jumping up and down saying of course, Your
10:32 3 Honor, the FDA says that it is preempted.

10:32 4 I understand with respect to the change from
10:32 5 warning requirement to a minimum warning requirement. The
10:32 6 FDA did give an additional reason for that. I mean, the
10:33 7 upshot is the same. The upshot is that it is a minimum
10:33 8 warning requirement, and parties are free to add additional
10:33 9 warnings. You know, I think it's very difficult to say that
10:33 10 manifests an intent to preempt when again it's simply a
10:33 11 minimum warning requirement. I think those two play
10:33 12 together.

10:33 13 Of course the FDA's determination on this point is
10:33 14 entitled to -- you know, I think we talked about the Chevron
10:33 15 deference in our paper, and that's the type of deference
10:33 16 that would be afforded here, especially here when the real
10:33 17 preemptive force of the regulation depends on what type of
10:33 18 requirement we are talking about. Is it a general
10:33 19 requirement as to all tobacco products, or is it a specific
10:33 20 requirement as to e-cigarette products? I think the FDA is
10:34 21 in a very good position to opine as to what type of
10:34 22 requirement it is. They did so and determined it's a
10:34 23 minimum warning requirement.

10:34 24 So, Your Honor, unless you have questions for me,
10:34 25 I'm done. Thank you.

10:34 1 THE COURT: Thank you.

10:34 2 Mr. Gabriel. First of all, what about the timing
10:34 3 issue?

10:34 4 MR. GABRIEL: With respect to the effective date?

10:34 5 THE COURT: Correct.

10:34 6 MR. GABRIEL: First, let me just say what the
10:34 7 Court has already indicated. None of this was argued in
10:34 8 their opposition to the motion, so it's an argument that I
10:34 9 am happy to respond to. I can do it extemporaneously.

10:34 10 THE COURT: Well, it has not been briefed. I
10:34 11 frankly would like to give the parties an opportunity to
10:34 12 brief the timing issue.

10:34 13 MR. GABRIEL: Okay. Let me address part of it.
10:34 14 One of the arguments being made here is that whatever may
10:34 15 happen in the future, for example, damages, some kind of
10:35 16 positive injunctive relief this Court orders, has a label
10:35 17 that says or has a Prop 65 warning. It seems to me what is
10:35 18 preempted are all requirements related to labeling in
10:35 19 addition to or different from. And whenever those
10:35 20 requirements are imposed by virtue of a finding of liability
10:35 21 after the rule has been adopted, that's what is preempted.

10:35 22 The idea that two years from now or six months
10:35 23 from now or nine months from now this Court imposing some
10:35 24 liability or a jury based upon a state requirement under an
10:35 25 unfair competition law that would be preempted, if it's

10:35 1 after the date of the rule be adopted, the field has been
10:35 2 preempted irrespective of the effective date of the rule.

10:35 3 THE COURT: Well, query. It seems to me if you
10:35 4 are arguing preemption on the basis of the regulation -- how
10:36 5 can it do that before it goes into effect? -- I can see the
10:36 6 argument that the regulation even if it's not in effect
10:36 7 suggests a conflict preemption or some other basis for
10:36 8 preemption, but direct preemption when the rule isn't in
10:36 9 effect --

10:36 10 MR. GABRIEL: Your Honor is previewing what we
10:36 11 would intend if you give both parties the opportunity to
10:36 12 brief it. I can articulate what the Court just said. There
10:36 13 are other arguments that arise from it. I am happy to do
10:36 14 it, but it seems to me it would be better to be dealt with
10:36 15 in briefing.

10:36 16 THE COURT: I agree.

10:36 17 MR. GABRIEL: Let me start with what I agree with
10:36 18 what counsel said. It is absolutely true that the gravamen
10:36 19 of all these claims is a failure to warn. What has been
10:36 20 conflated here by the plaintiff is what is this case about?
10:36 21 What are the claims? Plaintiffs' counsel keeps referring
10:36 22 to, well, there is the exposure to part, and there is the
10:36 23 failure to warn part, the exposure and use part.

10:37 24 He made some comment about, well, you know what,
10:37 25 we are going to have show and the claim here is that the use

10:37 1 and exposure results in some harm. There is no claim here
10:37 2 at all -- you can read every word of the 200-paragraph
10:37 3 Second Amended Complaint -- that any of the plaintiffs have
10:37 4 been harmed by virtue of exposure. No claim.

10:37 5 In fact, the specifics in the Complaint are that
10:37 6 somehow the plaintiffs have been misled into believing, gee,
10:37 7 this may be okay for me. There is no claim here that the
10:37 8 plaintiffs have been harmed by anything other than the
10:37 9 failure to warn. That's not only the gravamen of all the
10:37 10 claims, but that is the complete universe of all the claims.
10:37 11 So this dichotomy that has been set up -- well, we have got
10:37 12 two separate things going on here. We have got the
10:37 13 failure-to-warn claim, and then we have got the use and
10:37 14 exposure claim -- no, that's not true, Your Honor.

10:37 15 The Complaint is crystal clear. There is no
10:38 16 claim here -- no plaintiff is saying as part of a putative
10:38 17 class action I have been harmed because I'm sick. I will
10:38 18 live less long. It's simply why didn't somebody tells us in
10:38 19 a warning on the packaging or labeling that this could be
10:38 20 harmful?

10:38 21 The same thing is true for Prop 65. There is no
10:38 22 cause of action for any plaintiff under Prop 65 for exposure
10:38 23 or use. The cause of action exists simply by virtue of a
10:38 24 failure to use a mandated State warning in the event that
10:38 25 the exposure to a list of 800 different chemicals that the

10:38 1 State has promulgated exceeds a certain limit. It's a
10:38 2 failure-to-warn claim. There is no claim in the case that
10:38 3 any plaintiff has been harmed by exposure to formaldehyde.
10:38 4 None. It's simply we should have been warned. And when we
10:39 5 read only a nicotine warning, that wasn't good enough for
10:39 6 us. We should have been told something more.

10:39 7 So the idea that there are two separate things
10:39 8 here I believe is incorrect. An extremely careful reading
10:39 9 of the Second Amended Consolidated Complaint will confirm
10:39 10 that. And I think the Court's analysis in the tentative not
10:39 11 just about the gravamen but what all the claims are about,
10:39 12 is correct. This is about a failure to warn, all of them
10:39 13 articulated under a variety of different names. Whether
10:39 14 it's UCL or some Illinois statute, they all relate to the
10:39 15 same thing.

10:39 16 And the same thing is true for Prop 65. There is
10:39 17 no liability under Prop 65 for exposing anyone in California
10:39 18 to a chemical. The liability is it's in there. It's in
10:39 19 there in an amount that exceeds a safe harbor. Under those
10:39 20 circumstances, the failure to use a statutorily or a
10:39 21 California regulation-compelled warning is where the
10:39 22 liability is. That's where the penalty is. That's where
10:39 23 the remedy is. Not simply because you are exposing someone
10:40 24 to the chemicals.

10:40 25 With respect to the distinction about Medtronic

10:40 1 and the suggestion that Your Honor has conflated, the
10:40 2 general versus specific as between product and the warning
10:40 3 itself, in Your Honor's tentative, quoting from Medtronic,
10:40 4 this is the distinction that Medtronic makes. I'm reading
10:40 5 from the Court's decision. The Court held: "The generality
10:40 6 of those requirements" -- the requirements were to include
10:40 7 with a device a label containing information for use any
10:40 8 relevant hazards, contraindications, side effects. That's a
10:40 9 list of generalities. The Court says: "The generality of
10:40 10 those requirements made this quite unlike a case in which
10:40 11 the federal government has weighed the competing interests
10:40 12 relevant to the particular requirement in question reaching
10:40 13 an unambiguous conclusion about how these competing
10:40 14 considerations should be resolved in a particular case or
10:41 15 set of cases and implemented that conclusion via a specific
10:41 16 mandate on manufacturers or producers."

10:41 17 How much more of a specific mandate can we have
10:41 18 than here is the warning for nicotine? Here's how big it
10:41 19 has to be. Here's where it has to go. So this
10:41 20 circumstance, as the Court points out in the tentative, is
10:41 21 clearly distinguishable from the Lohr case where all Lohr
10:41 22 was talking about is you have got to include something on
10:41 23 your label about how you use the product, anything about
10:41 24 hazardous. That's general. The specific here relates to
10:41 25 the nature of the specific mandate.

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10:41 1 The argument, well, a lot of different things are
10:41 2 covered by the definition of tobacco products, so ipso facto
10:41 3 it's general because it covers gels and other things -- if
10:41 4 we had nine statutes and they were all separate, and one was
10:41 5 for electronic cigarettes and another one was for e-liquids
10:42 6 and another one was for gels, that would make a difference?
10:42 7 I don't think the argument makes any sense. I think the
10:42 8 Court has it right, which is the Lara case is absolutely
10:42 9 clearly distinguishable.

10:42 10 As to the whole concept of what the FDA was saying
10:42 11 or not saying in that statement, I think the Court is
10:42 12 correct. I think it's very simple. All 29 Attorney
10:42 13 Generals asked for something. There were a lot of different
10:42 14 comments. Reading the English language of that statement,
10:42 15 the FDA has not made a determination with respect to any
10:42 16 statute. Why would it because the circumstances could be a
10:42 17 myriad?

10:42 18 They were asked to make a determination -- the FDA
10:42 19 was asked to make a determination with respect to Prop 65,
10:42 20 and it didn't. The idea that that turns into so therefore
10:42 21 it's not preempted doesn't make sense. There is no
10:42 22 authority -- we haven't seen any -- for the proposition that
10:42 23 if the FDA says we haven't made a determination that that
10:43 24 means it's not preempted.

10:43 25 I think the plain English of that sentence reads

10:43 1 exactly the way it states, which is one way or another we
10:43 2 haven't determined. As I said, why would it? Under the
10:43 3 circumstances of a final rule -- with all kinds of different
10:43 4 requests for different scenarios, either specifically -- why
10:43 5 don't you determine that this is not preempted? -- or
10:43 6 generally, the FDA says we haven't made that determination.

10:43 7 With respect to the minimum requirement on the
10:43 8 label issue, we briefed this, Your Honor. The reason that
10:43 9 word was changed to "minimum" was the FDA explained the
10:43 10 reason. There were two reasons. One is there are already
10:43 11 companies voluntarily doing other things or other warnings.

10:43 12 As counsel said, parties are free to add
10:44 13 additional warnings. That's right. That's what the FDA
10:44 14 said. An individual manufacturer can "voluntarily" --
10:44 15 that's the FDA's word -- have additional warnings, or the
10:44 16 FDA may if it decides to require additional warnings. The
10:44 17 parties don't include a state requirement to add warnings.

10:44 18 THE COURT: The parties' flexibility doesn't
10:44 19 translate into a carte blanche or state regulation.

10:44 20 MR. GABRIEL: Your Honor said it better than I
10:44 21 tried to say it five sentences. I agree, Your Honor.

10:44 22 One thing I wanted to point out just for the
10:44 23 Court's information is there is a discussion in the
10:44 24 Advertising Section of the tentative that deals with one
10:44 25 type of warning that Prop 65 authorizes, which is the

10:44 1 warning related to signs. Let me direct the Court's
10:44 2 attention to that. This is at the bottom of page nine and
10:45 3 the top of page ten. It says: "Defendants may comply with
10:45 4 a Prop 65 warning by a system of signs, public advertising,
10:45 5 identifying the system, and toll-free information." And
10:45 6 that was true at the time that the briefs were submitted.

10:45 7 The day after the reply brief was submitted by the
10:45 8 defendants, Your Honor, the California Office of
10:45 9 Environmental Health, Hazard, and Assessment released final
10:45 10 amendments to those rules. The section cited which
10:45 11 addresses signs -- the types of warning requirements -- has
10:45 12 been replaced by a new section. That new section deletes
10:45 13 anything having to do with signs or 800 numbers. We can
10:45 14 submit this, Your Honor. I didn't want to add to the paper
10:45 15 already before the Court.

10:45 16 That warning requirement -- the ability to warn
10:45 17 based upon what is being pointed to by the plaintiff will be
10:46 18 gone. Instead, there will be a new set of warnings. These
10:46 19 were as I said -- the section that is cited, Section 25603.1
10:46 20 of Article VI, has been replaced by a new section. In any
10:46 21 event, it's just a point of information for the Court.

10:46 22 I understand the Court's ruling with respect to
10:46 23 the Lemman case, the critique in Lemman of the Ninth Circuit
10:46 24 case. The Court recognizes in its ruling that there may be
10:46 25 some arguments about the applicability of the Ninth Circuit

10:46 1 opinion, but I will not try to argue with the Court about
10:46 2 being bound by the Ninth Circuit ruling in that case.

10:46 3 It seems to me, Your Honor, that the Court in its
10:46 4 tentative has nailed it in terms of exactly what is going on
10:46 5 here. This is a set of claims by a putative class
10:47 6 essentially saying had you told us that this product could
10:47 7 hurt us beyond telling us about nicotine we would have done
10:47 8 something different. It's about warnings. There is no
10:47 9 claim about harm.

10:47 10 The notion that it's exposure to or use as the
10:47 11 predicate for this case is not what this case is about. It
10:47 12 is a failure to warn a group of people about so-called
10:47 13 additional dangers. All of those claims as the Court points
10:47 14 out are predicated upon labeling or packaging deficiencies.
10:47 15 That's what the FDA has decided, and that's what the statute
10:47 16 preempts, labeling. It makes sense, Your Honor.

10:47 17 Just if I may divert slightly from the record to
10:48 18 food labeling. We all buy food, and we see that little box
10:48 19 that has in it all the things that the FDA believes we
10:48 20 should know about, which is what's a serving? How many
10:48 21 servings in a package? That's specific labeling
10:48 22 requirements. That can't be touched by any state because
10:48 23 the FDA has determined its exclusive jurisdiction with
10:48 24 respect to that.

10:48 25 That's what is going on with cigarettes. The

10:48 1 states have plenty of power to co-regulate. That's what the
10:48 2 exemptions from the preemption is all about. Exposure to,
10:48 3 use of, all relates to where should the product be in the
10:48 4 store? How old do you have to be to buy the product? Who
10:48 5 can be in the ads? Does it have to be an adult? Does it
10:48 6 have to be somebody over 30? The state has all kinds of
10:48 7 powers which the State of California is happily exercising,
10:48 8 including most recently, related to what it can do.

10:49 9 That is consistent with what counsel has
10:49 10 represented to the Court the FDA's theory of regulations.
10:49 11 The states can come and join in and regulate. But what the
10:49 12 states can't do and what this rule is all about is the state
10:49 13 can't get involved with requirements that are different from
10:49 14 or in addition to labeling requirements. We have the most
10:49 15 specific type of requirement you can have: where it goes in
10:49 16 the labeling, what it says, how big it needs to be.

10:49 17 If the FDA some day determines there should be
10:49 18 more warnings as it has indicated it is contemplating, it
10:49 19 will do so. If manufacturers want to voluntarily put more
10:49 20 warnings on the labels or packaging, they can do so. What
10:49 21 the state can't do by virtue of liability through Prop 65 or
10:49 22 through a class action or otherwise is create a circumstance
10:49 23 where anybody can sue and take the position that I should
10:49 24 have learned more from the packaging and labeling and I
10:49 25 didn't, so now I will have a claim. You will have 50 states

1 interpreting their own laws and determining what should or
2 should not be on a label.

3 Your Honor, we would submit on the tentative. If
4 the Court wants more briefing on the issues that were
5 raised, we can respond to them.

6 One comment about Judge Carter's decision and
7 maybe we can brief that as well. I think so far I'm in
8 agreement with everything I heard, which is I don't quite
9 understand where the Court came up with the idea that
10 labeling means a point of origin only, and that's the only
11 thing that's preempted under the definition of "labeling" in
12 this particular statute. I don't see that anywhere.
13 Counsel has kind of speculated about that. I think the case
14 is clearly distinguishable. It doesn't really have any
15 impact on the decision of the Court.

16 We are willing to accept the tentative. If the
17 Court wants some briefing on the other issues, that's fine.

18 I would like to remind the Court this entire
19 action has been stayed except for the pleading stage. The
20 defendants suggested to the Court it should have just been
21 stayed completely independent of any ferreting out of the
22 pleadings. I think what happened is the fortuity of --
23 here's the final rule that came out afterwards, after a
24 Second Amended Consolidated Complaint. So the defendants
25 obviously felt compelled to brief the preemption issue. We

10:51 1 certainly didn't want to waive it. But now we are entering
10:51 2 an arena that -- you know, this is where we are.

10:51 3 So I think it's important that the Court does rule
10:51 4 on this motion. I think it will make a difference in the
10:51 5 real world for the parties. And if there is some notion
10:51 6 that we should wait yet again, which is essentially what
10:51 7 plaintiffs' counsel is suggesting, why doesn't plaintiffs'
10:51 8 counsel dismiss the case without prejudice, and it can wait
10:51 9 and see --

10:51 10 THE COURT: Well, there are obviously tolling
10:51 11 problems, but --

10:51 12 MR. GABRIEL: The argument that, by the way, there
10:51 13 is an attack on the regulations, why don't we kind of wait
10:51 14 and see what happens with that. You know, there is an
10:51 15 attack on the IRS by different taxpayers claiming it's
10:52 16 unconstitutional, so --

10:52 17 THE COURT: But you probably still pay your taxes
10:52 18 every April 15.

10:52 19 MR. GABRIEL: Correct. That's right.

10:52 20 Let me make some final comment about this. Again,
10:52 21 I would concede it's outside the record. The plaintiffs
10:52 22 asserting the Prop 65 cases -- you know, they're not sitting
10:52 23 back to wait and see what happens. Whether it's in this
10:52 24 class action or the plaintiffs that are filing pure Prop 65
10:52 25 cases, they are actively litigating against the defendants

10:52 1 claiming that there are violations of the statute
10:52 2 notwithstanding the rule being promulgated.

10:52 3 I just don't see a circumstance where in the
10:52 4 future a Court can impose either damages or injunctive
10:52 5 relief addressing the issue of labeling, not after there has
10:52 6 been a final rule adopted by the FDA, which we believe
10:52 7 preempts all of that activity.

10:52 8 Thank you, Your Honor.

10:52 9 THE COURT: Thank you.

10:53 10 Mr. Todzo, you have five minutes.

10:53 11 MR. TODZO: Thank you, Your Honor.

10:53 12 I don't really have that much to add. I just
10:53 13 thought what is interesting was with respect to does the
10:53 14 case relate to exposure at all? Mr. Gabriel was saying that
10:53 15 no, no, no, everything is based on a failure to warn. But
10:53 16 failure to warn about what? It's a failure to warn about
10:53 17 certain things that happens when users are exposed to the
10:53 18 products. So it's that second part that -- if we end up
10:53 19 saying --

10:53 20 THE COURT: Well, isn't there a difference between
10:53 21 claiming I used these devices and was exposed to
10:53 22 formaldehyde and have some chronic lung disease as opposed
10:53 23 to you didn't warn me, and if you had, I wouldn't have used
10:53 24 them? Aren't those distinct?

10:53 25 MR. TODZO: No doubt those are different. But the

10:54 1 second one, that if you had told me that my use or exposure
10:54 2 to these products would cause me harm, I still as a
10:54 3 plaintiff proving that case -- just I wouldn't have bought
10:54 4 the product if you had told me that, I still need to prove
10:54 5 that use or exposure results in something. I need to show
10:54 6 that it results in some type of harm that I have now an
10:54 7 increased risk of.

10:54 8 THE COURT: They may be a common element, but they
10:54 9 are distinct claims. One is essentially a personal injury
10:54 10 claim, and one is a statutory claim for failure to disclose.

10:54 11 MR. TODZO: I just come back to failure to
10:54 12 disclose about what? They has to be something that they
10:54 13 failed to disclose. They had to fail to disclose adverse
10:54 14 health effects from use of the products.

10:54 15 THE COURT: I agree with you that there is a
10:54 16 common element, but in terms of what the claim is, you
10:54 17 failed to tell me this was harmful, yes, and you are going
10:54 18 to have prove that it was harmful. If you are saying I was
10:55 19 exposed to this and I was harmed, yes, you are going to have
10:55 20 to prove it was harmful, but you are going to have to prove
10:55 21 that the plaintiff was in fact harmed. That's different.

10:55 22 MR. TODZO: I agree that there is a difference,
10:55 23 but they both still relate to exposure, especially again on
10:55 24 the Prop 65 where we need to prove that. That's an element
10:55 25 of our case.

10:55 1 With respect to -- I think maybe it does make
10:55 2 sense to brief the timing issue. Again, there is nothing --
10:55 3 Mr. Gabriel's idea that -- you know, imposition of a
10:55 4 remedy -- somehow that's what is preempted -- again, that
10:55 5 would be imposition of a labeling remedy, i.e., injunctive
10:55 6 relief, but that speaks nothing to damages dating back.
10:55 7 Again, that's something we can brief for Your Honor.

10:55 8 I think that's it for now.

10:56 9 THE COURT: Okay. Well, how about concurrent
10:56 10 briefs, 15 pages, dealing with this timing issue. If you
10:56 11 want to deal with Judge Carter's decision as part of that 15
10:56 12 pages, that's fine. I won't restrict you from going into
10:56 13 that.

10:56 14 How much time would you like to generate those
10:56 15 briefs?

10:56 16 MR. GABRIEL: Ten days or a week. It's a new
10:56 17 issue.

10:56 18 THE COURT: Yes, it is. The case is stayed for
10:56 19 all other purposes, so I don't think we are actually under
10:56 20 the gun time wise. You tell me what you want.

10:56 21 MR. GABRIEL: Ten days.

10:56 22 MR. TODZO: Let me see my calendar first.

10:56 23 THE COURT: Why don't we say Monday, the 26th. Is
10:56 24 that enough time?

10:57 25 MR. GABRIEL: That's fine with me.

10:57 1 MR. TODZO: Yes, Your Honor.

10:57 2 THE COURT: Okay, 15 pages. And the matter will

10:57 3 stand submitted once we received the supplemental briefs.

10:57 4 MR. TODZO: Thank you, Your Honor.

10:57 5 MR. GABRIEL: Thank you, Your Honor.

10:57 6 (Whereupon, the proceedings were concluded.)

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CERTIFICATE

I hereby certify that pursuant to Section 753,
Title 28, United States Code, the foregoing is a true and
correct transcript of the stenographically reported
proceedings held in the above-entitled matter and that the
transcript page format is in conformance with the
regulations of the Judicial Conference of the United States.

Date: September 28, 2016

/s/ Sharon A. Seffens 9/28/16

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